IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Shunji Natsuka, et al. Application No.: 10/700,505 Filed: November 5, 2003 For: MURINE ALPHA (1,3) FUCOSYLTRANSFERASE FUC-TVII, DNA ENCODING THE SAME, METHOD FOR PREPARING THE SAME, ANTIBODIES RECOGNIZING THE SAME, IMMUNOASSAYS FOR DETECTING THE SAME, PLASMIDS CONTAINING SUCH DNA, AN CELLS CONTAINING SUCH PLASMID Customer No.: 20350	Confirmation No. 9880 Examiner: Taeyoon Kim Technology Center/Art Unit: 1651 **DECLARATION UNDER 37 C.F.R. § 1.131**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. I, John B. Lowe, was at the time of the invention employed by the Howard Hughes Medical Institute. I was also a faculty member of the University of Michigan, and the Regents of the University of Michigan, were the assignee of the above-referenced patent application. My co-inventors, Kevin M. Gersten and Shunji Natsuka, were employed by the University of Michigan, and by the Howard Hughes Medical Institute, respectively. At the time of the invention, I was a Howard Hughes Medical Institute Investigator of my own laboratory and supervisor to Kevin Gersten and Shunji Natsuka. Kevin Gersten was a graduate student and Shunji Natsuka a postdoctoral student in my laboratory. I am, with my co-inventors, a named and true inventor of the subject matter disclosed and claimed in the above-referenced patent application.

2. The present invention provides a murine fucosyltransferase-VII ("Fuc-TVII") enzyme comprising a catalytic domain, wherein the enzyme has fucosyltransferase activity and is

encoded by a nucleic acid sequence segment that is identical to a polynucleotide that is amplified using murine mRNA or cDNA as a template by a 5' primer as shown in SEQ ID NO:3 (GCGCGGATCCCACCATCCTTATCTGGCACTGGCCTTTCACC) and a 3' primer as shown in SEQ ID NO:4 (GCGCGGATCCAGTTCAAGCCTGGAACCAGCTTTCAA GGTCTTC).

3. I, with my co-inventors, conceived of and reduced to practice the claimed invention in the United States prior to June 7, 1995, the filing date of U.S. Patent No. 5,858,752. I am submitting this Declaration because the Examiner has requested further evidence that the "phage 104" discussed in the laboratory notebook pages from Kevin Gersten and earlier presented as Exhibit B contains the sequence of mouse fucosyltransferase VII (FucT-VII). The evidence accompanying this Declaration is from notebooks of my laboratory and dated prior to the June 7, 1995 filing date of U.S. Patent No. 5,858,752.

4. The attached Exhibits C, D, E and F are pages and analyses from the laboratory notebooks of Kevin Gersten and Shunji Natsuka, dated prior to June 7, 1995, providing evidence showing that phage 104 contained the mouse FucT-VII gene.

5. Exhibit C provides copies of orders of primers used to sequence the mouse FucT-VII gene from phage 104. The primers were ordered by co-inventor Kevin Gersten for the purpose of sequencing phage 104. In the "User Comments" section of the orders, Kevin Gersten interchangeably refers to FucT-VII or phage 104. The primer sequence number or system identification number is indicated in the upper right hand corner of the orders. The primers, named according to their sequence number or system identification number, are listed in the order of their appearance (5′ to 3′) along the length of the mouse FucT-VII gene in Exhibit D.

6. Exhibit E provides the full-length nucleic acid sequence of the mouse FucT-VII gene, as sequenced from phage 104, annotated with the sequence identification numbers of the primers used by Kevin Gersten. The primer sequences are identified by bolded text. The primer sequence identification number is above the sequence for forward primers and below the sequence for reverse primers. Start and stop codons and relevant restriction endonuclease sites are also identified.

7. Exhibit F shows a notebook page from co-inventor Shunji Natsuka, who used a segment of the mouse FucT-VII gene in phage 104 to clone the human FucT-VII gene. On the notebook page presented, Dr. Natsuka records using a fragment from the FucT-VII gene in phage 104 to hybridize to human genomic DNA in a Southern blot. At the top of the page, Dr. Natsuka correlates phage 104 with mouse FucT-VII.

8. In view of the foregoing, I respectfully submit that the evidence provided in Exhibits C-F unequivocally establishes that phage 104 contained the FucT-VII gene. The combined evidence in Exhibits A-F unequivocally establishes that the claimed invention was conceived of and reduced to practice prior to June 7, 1995.

9. I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that any such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

10. The Declarant has nothing further to say.

Dated: 10-19-07

John B. Lowe

Attachments
JLW:jlw
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